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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/894,356	08/18/1997	TOSHIHIKO ASHIKARI	001560-308	8892

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/894,356	ASHIKARI ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,5-12,20,22-25,27-41,54-62 and 64-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *54-62 and 64-67* is/are allowed.

6)☒ Claim(s) *2,3,5-12,20,22-25,27-41,68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 10/04/05 in reply to the Office action of 04/04/05 has been entered. The Sequence Listings of 10/04/05 have been entered. Claims 2, 5-8, 11, 28, 31-32, 37-38, 54, 57, 64 are amended. New claim 68 is added. Therefore, 2-3, 5-12, 20, 22-25, 27-41, 54-62, and 64-68 are pending and are considered.

All previous rejections and objections not set forth below have been withdrawn in view of Applicant's amendment.

Claim Objections

Claims 2-3, 5-6 are objected for failing to further limit parent claim 7. This objection is repeated for the reasons of record. Applicant argues that the claims further limit parent claim 7 because Applicant asserts that the claims recite a specific sequence as well as other characteristics. Therefore, Applicant requests, withdrawal of the objection (paragraph bridging pages 10-11 of the response).

This is not found persuasive. Claim 7 is directed to an isolated polynucleotide encoding an anthocyanin acyltransferase having at least 30% homologous to SEQ ID NO: 32-37 and which transfers an aromatic acyl group to the glucose of the 3 or 5 position of anthocyanin. Claims 2 and 3 are product by process claims and recite no specific sequence for the polynucleotide. The SEQ ID NO: 21 is used as a primer in the process that produces the polynucleotide. Therefore, claims 2-3 do not further limit parent claim 7. Claims 5-6 recite that polynucleotide of claim 7 hybridizes to a sequence

encoding SEQ ID NO: 21 or all of the nucleotide sequence encoding any of SEQ ID NO: 32-37 under specified hybridization conditions. A polynucleotide that hybridizes to a polynucleotide encoding SEQ ID NO: 21 does not further limit the polynucleotide of claim 7 because the former is only 17 nucleotides long and cannot encode a polypeptide having an anthocyanin acyltransferase. In addition SEQ ID NO: 21 is not specific to the aromatic acyltransferase. A polynucleotide that hybridizes to all of the nucleotide sequence encoding any one of SEQ ID NO: 32-37 does not further limit a polynucleotide encoding a protein having at least 30% homologous to SEQ ID NO: 32-37. In addition, due to codon degeneracy, the claimed polynucleotide would not hybridize to all of the nucleotide sequence encoding any one of SEQ ID NO: 21 and 32-37. Therefore, the polynucleotides of claims 4 and 5 further broaden the scope of the polynucleotide of claim 7. Therefore, the objection is proper.

Claim Rejections - 35 USC § 112

Claims 2-3, 25 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite in the recitation of "used" as the claim do not recite how the primer is used. It is suggested that "used" be deleted.

Claims 25 and 27 refer to cancelled claim 1 (as stated for claim 8 in the last Office action). Appropriate correction is required to more clearly define the metes and

bounds of the claims. In the interest of compact prosecution, claim 25 is considered to depend upon claim 7.

Claim Rejections - 35 USC § 112

Claims 2-3, 5-12, 20, 22-25, 27-41 and 68 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling for claims limited to the isolated polynucleotide encoding any one of SEQ ID NO: 32-37, a recombinant vector, plant cell/tissue/cut flower, microbial cell, plant comprising it, and a method of transforming a plant with said vectors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in previous Office action of 04/04/05, 03/09/04 and 02/22/02. Applicant's arguments filed 10/04/05 have been considered but are not deemed persuasive.

Applicant contends that no working examples are necessary in any specification for enablement. Applicant asserts that six working examples that are disclosed in the specification should be sufficient to enable the broad scope of the claims. Applicant cites MPEP 2164.02 and Training Materials for Examining Patent Applications With respect to enablement to support his position (response, p. 13).

These are not persuasive because Applicant was never required to exemplify each and every claimed embodiment. MPEP 2164.02 states "(T)he specification need not contain an example if the invention is otherwise disclosed in such manner that one

skilled in the art will be able to practice it without an undue amount of experimentation. In re Borkowski, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). Lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art. But because only an enabling disclosure is required, applicant need not describe all actual embodiments." Also, the Federal circuit has repeatedly held that the "specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation (In re Fisher, 427 F .2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)).

The claims are rejected because the scope of the enabling disclosure is not commensurate with the scope of the claims. The instant specification does not provide guidance regarding how to produce variants that retain the anthocyanin acyltransferase function. There is also a complete lack of guidance in the specification and in the prior art as to how and where the disclosed sequences can be modified to produce a polynucleotide encoding a protein that is at least 30% or 69% homologous to SEQ ID NO: 32-37, while retaining the desired activity, as stated in the last Office action.

Applicant asserts that instant claims are distinguishable from the facts in Amgen in that Amgen was unable to specify analogs with the desired biological properties and that the science was more than a decade prior to the science of the instant invention. Applicant also asserts that the instant specification provides numerous species of acyltransferase and process of determining acyltransferase activity (response, p. 14).

This is not found persuasive. In *Amgen v. Chugai Pharm.* Co., 927 F. 2d 1200, 18 USPQ2d 1016 (Fed. Cir 1991), the court has determined that the specification didn't

give those skilled in the art guidance as to which amino acids could be changed to either preserve or enhance the activity of the protein. Like in Amgen, the instant specification is completely silent as to any modifications to the disclosed that can produce even one variant having a property and function as recited in the claims. Applicant points to specific methods or science that shows sequence modifications in acyltransferase was routine at the time this application was filed. Because a very small change in the amino acid sequence of a protein can result in a very large change in the structure-function activity of a protein. Therefore, given this highly unpredictable areas and lack of sufficient guidance in the specification and in the prior art, one skilled in the art would have to proceed with undue trial and error experimentation to screen through a vast number of polynucleotides encoding proteins with multiple of amino acid modifications to identify those having the functional activity of SEQ ID NO: 32-37. Undue experimentation would also be required to determine the ability of each of modified sequence to alter, acylate or stabilize a plant pigment upon expression in a transgenic plant.

Applicant argues that Example 11 of the specification uses the primer of SEQ ID NO: 22 to identify and isolate an acetylytransferase from *Perillas* in Example 11 of the specification. Applicant, therefore asserts, that no prima facie case of lack of enablement was established in this case (response, p. 14).

This is not found persuasive because in Example 11, SEQ ID NO: 22 was used with specific PCR conditions which are not recited in the rejected claims. In addition,

claims 2 and 3 are product by process rather than a process that employs SEQ ID NO: 22 to isolated acyltransferases.

Applicant also argues against the rejection to the hybridizing sequences by citing US Patents 6, 949,693 and US Pat 6, 878, 859 with claims drawn to hybridizing sequences.

This is not found persuasive for two main reasons: firstly, unlike the claims of the issued patent, claims 5-6, 28 and 68 require that the polynucleotide hybridize to all of the nucleotide sequence encoding any one of SEQ ID NO: 21, 32-37. Given the degeneracy of the code, many of the polynucleotides that encode SEQ ID NO: 21, and 32-37 are significantly divergent from the polynucleotides of SEQ ID NO: 22 and 1-6, respectively. Therefore, a polynucleotide that hybridize to SEQ ID NO: 22 and 1-6 may not hybridize to other polynucleotide encoding SEQ ID NO: 21 and 32-37. Secondly, unlike the instant claims, the hybridization conditions recited in the issued claims define highly stringent. Secondly, Examiner notes that there is no relationship between the caryopsis-specific promoter or the isoflavonoid methyltransferase of the issued patent and the anthocyanin acyltransferase of the instant application. In addition, Examiner notes that every patent application is examined upon its own merit and according to the rules and regulations of the USPTO at the time the application is filed.

Therefore, given the breadth of the claims; the lack of guidance as discussed supra and in the last Office actions; the unpredictability with regard to amino acid modifications; and the limited working examples, the claimed invention is not enabled throughout the broad scope (*In re Wands 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir.*

1988).

Written Description

Claims 2-3, 5-12, 20, 22-25, 27-41 and 68 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in previous Office actions of 04/04/05, 03/09/04 and 02/22/02. Applicant's arguments filed 10/04/05 have been considered but are not deemed persuasive.

Applicant maintains his arguments that the claimed invention satisfies the written description requirement. Applicant specifically argues that the disclosed six complete nucleic acid sequences encoding six complete polypeptides with a known functional activity, namely acyltransferase, from different plant species and the methods for identifying additional sequences are sufficient to describe the claimed genus of polynucleotide sequences (response, p. 16).

This is not found persuasive because the specification does not describe a representative number of species of the genus claimed for the reasons set forth in the last Office actions. Applicant correctly states the factual considerations that one must weigh when determining whether written description requirement is met. SEQ ID NO: 1-6 encoding SEQ ID NO: 32-37 are full length novel sequences with anthocyanin acyltransferase activity. On pages 3-4 of the specification, Applicant states that a gene

encoding a protein with anthocyanin acyltransferase activity was never isolated before Applicant's invention, much less of methods of using said genes to stabilize anthocyanin in a transgenic plant.

While the specification discloses the six polypeptides share only 30% homology with each, prior art search didn't reveal any significant sequence identity with any known polypeptide or family polypeptide. Applicant has not described any modifications to the disclosed sequences that retain the desired functional activity; nor that Applicant teaches functional domains in the full-length sequences that are responsible for the anthocyanin acyltransferase activity.

Given the vast number of polynucleotides encompassed by the claimed genus and the lack of any physical/chemical or any other relevant identifying characteristics for a polynucleotide that hybridizes under the conditions as recited in the claims to a polynucleotide encoding any one of SEQ ID NO: 21 and 32-37 and encoding anthocyanin acyltransferases, or polynucleotides encoding proteins that are 30% and 60% homologous to any of SEQ ID NO: 32-37 and retaining anthocyanin acyltransferases activity; and because the specification does not disclose a single variant with less than 100% homology to SEQ ID NO: 1-6 and 32-37 with anthocyanin acyltransferase activity, and the prior art is silent with respect to functional domains in the full-length sequences that are responsible for the anthocyanin acyltransferase activity, the disclosed six sequences are insufficient to describe polynucleotides encoding proteins that are 30% or 69% homologous to SEQ ID NO: 32-37, and

polynucleotides hybridize to all of the nucleotide sequence encoding any one of SEQ ID NO: 21, 32-37 and encoding an anthocyanin acyltransferase activity.

Therefore, for all the reasons discussed above and in the last Office actions, the claimed invention is not adequately described. Therefore, the rejection is maintained.

Remarks

The claims are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide encoding a protein that is 30% homologous to any of SEQ ID NO: 21 and 32-37; or an isolated polynucleotide that hybridizes to any of the disclosed sequences as recited in the claims, host cells, plants/plant cells comprising said polynucleotide; nor that the prior art teaches a method that employs said polynucleotide.

Claims 54-62 and 64-67 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

12/23/05
Mai

MEDINA A. IBRAHIM
PATENT EXAMINER
Medina A. Ibrahim